510(k) Summary for Mission Diagnostic Fluid Packs on MEDICA Electrolyte Analyzers

K031159

1. **Submitter's Name & Address**

Mission Diagnostics
331 Fiske St
Holliston MA 01746
FAX: 508-429-0452

Contact Person:
Linda Stundtner
QA/RA Manager
508-429-0450

Establishment Registration Number: 3003656721

Date of Preparation: April 11, 2003

2. **Identification of the Device:**

Proprietary/Trade name:	Calibrating Material, Calibrating standards
Common or usual name	Calibrator Pack, Fluid Pack for ISE automated systems
Classification name:	Calibrator, secondary
Device Classification	II
Regulation Number:	21 CFR § 862.1150
Panel:	Chemistry (75)
Product Code:	JIT

- Mission manufactures calibrators intended to serve as direct replacements to like named products manufactured by Original Equipment Manufactures (OEM)

3. **Predicate Device:**

- Mission claims substantial equivalence to the predicate device, Electrode, ion-specific, sodium; EasyLyte Na,K,Cl, Li Analyzer; K963763, MEDICA CORP.

Substantial Equivalence Table of Product PN's & Trade Names

Mission Product		Predicate Device	
ME-2120D & ME-2109D	Medica 800 & 400 ml Fluid Packs Na/K	2120 & 2109	Medica EasyLyte 800 & 400 ml Solutions Pack Na/K
ME-2121D & ME-2112D	Medica 800 & 400 ml Fluid Packs Na/K/Cl	2121 & 2112	Medica EasyLyte 800 & 400 ml Solutions Pack Na/K/Cl
ME-2122D & ME-2115D	Medica 800 & 400 ml Fluid Packs Na/K/Li	2122 & 2115	Medica EasyLyte 800 & 400 ml Solutions Pack Na/K/Li
ME-2123D & ME-2114D	Medica 800 & 400 ml Fluid Packs Na/K/Ca/pH	2123 & 2114	Medica EasyLyte 800 & 400 ml Solutions Pack Na/K/Ca/pH
ME-2026D & ME-2028D	Medica 800 & 400 ml Fluid Packs Na/K/Cl/Li	2026 & 2028	Medica EasyLyte 800 & 400 ml Solutions Pack Na/K/Cl/Li
IL-2120D	ILyte 800 Fluid Pack Na/K	ME002120	IL Test™ 800 Solutions Pack Na/K
IL-2121D	ILyte 800 Fluid Pack Na/K/Cl	ME002121	IL Test™ 800 Solutions Pack Na/K/Cl
IL-2120D	ILyte 800 Fluid Pack Na/K/Li	ME002122	IL Test™ 800 Solutions Pack Na/K/Li
IL-2123D	ILyte Fluid Pak Na/K/Ca/pH	ME002123	IL Test™ 800 Solutions Pack Na/K/Ca/pH
IL-2026D	ILyte 800 Fluid Pack Na/K/Cl/Li	ME002026	IL Test™ 800 Solutions Pack Na/K/Cl/Li
MN-2120D	Menarini 800 Fluid Pack Na/K	Not Known	Spotlyte™ 800 Solutions Pack Na/K
MN-2121D	Menarini 800 Fluid Pack Na/K/Cl	Not Known	Spotlyte™ 800 Solutions Pack Na/K/Cl
MN-2120D	Menarini 800 Fluid Pack Na/K/Li	Not Known	Spotlyte™ 800 Solutions Pack Na/K/Li
MN-2123D	Menarini Fluid Pak Na/K/Ca/pH	Not Known	Spotlyte™ 800 Solutions Pack Na/K/Ca/pH
MN-2026D	Menarini 800 Fluid Pack Na/K/Cl/Li	Not Known	Spotlyte™ 800 Solutions Pack Na/K/Cl/Li

- The Mission Fluid Packs (PN = ME-XXXXD or IL-XXXXD or MN-XXXXD) are equivalent to the Medica EasyLyte Solutions Packs or IL Test™ Solutions Packs or Menarinin Spotlyte™ Packs. They are a self-contained closed reagent package containing all the calibrating and wash reagents. The Solutions Packs slide into the front of the instrument for operation.

4. Device Description:

- The Calibrators for the OEM Instruments are aqueous reagents with salts (chemical constituents) added to obtain desired analyte levels to provide the desired calibration.
- **Intended Use:**
- The reagents are intended for use in place of predicate devices.
- The original equipment manufacturer (OEM) of the instruments and the predicate reagents which are necessary for the continued operation and use of the instruments.
- Mission uses a similar composition, description and packaging as that used by the OEM in its products, as shown in the packaging section of this submission.

5. Performance Characteristics:

Precision and correlation data are collected per:

- SOP23-01-02 Performance Study Protocol for 510(k) Submission
- Data for each instrument and each run are recorded on SOP23-03F Performance Study Record Sheet. (See Attachment Section for Copy of Procedures)

Precision Data

Precision data were collected from the analysis of three levels of control materials during a minimum of two runs per day on the Medica analyzers calibrated with all Mission reagents and when calibrated with Medica reagents.

Data shows that QC precision with Mission Fluid Packs was substantially equivalent to the QC precision with Medica Fluid Packs.

MEDICA Precision Data w/ MISSION REAGENTS

Analyte	Level	N	Mean	sd	Min	Max	%CV
Na	1	12	115.1	3.0	110.0	121.1	2.6
	2	12	135.6	1.2	133.0	138.0	0.9
	3	12	159.6	2.8	156.0	166.0	1.8
K	1	12	2.05	0.07	1.97	2.19	3.5
	2	12	4.21	0.02	4.17	4.24	0.5
	3	12	6.63	0.05	6.48	6.69	0.8
Cl	1	12	72.3	2.6	67.9	77.0	3.6
	2	12	91.4	3.3	82.0	96.0	3.6
	3	12	114.3	4.9	102.0	118.0	4.3
Li	1	12	0.32	0.09	0.22	0.49	
	2	12	1.10	0.01	1.09	1.12	
	3	12	2.25	0.14	1.98	2.38	

MEDICA Precision Data w/ MEDICA REAGENTS

Analyte	Level	N	Mean	sd	Min	Max	%CV
Na	1	12	116.4	5.4	106.0	128.0	4.6
	2	12	136.8	3.5	131.0	142.0	2.5
	3	12	159.9	2.9	155.0	165.0	1.8
K	1	12	2.06	0.06	1.96	2.19	2.9
	2	12	4.23	0.02	4.19	4.26	0.5
	3	12	6.68	0.07	6.54	6.79	1.1
Cl	1	12	72.5	5.3	58.0	77.0	7.3
	2	12	91.6	6.0	73.0	97.0	6.5
	3	12	117.9	6.8	106.0	137.0	5.7
Li	1	12	0.34	0.08	0.26	0.32	
	2	12	1.12	0.01	1.10	1.12	
	3	12	2.17	0.09	2.15	2.29	

Correlation with Medica Fluid Packs

Correlation data were obtained from human serum samples for Na, K, Cl, Ca, and Li. Samples were then spiked to yield varying concentrations of each of the measuring analytes. The serum samples were measured on Medica EasyLytes calibrated with Mission Fluid Packs for 2 runs and Calibrated with Medica Fluid Packs for 2 runs each test day.

Linear regression analysis was performed using Mission data as the independent X variable and Medica as the dependent Y variable in the equation $Y = mX + b$ where m = slope, b = intercept

MEDICA Correlation Summary

Analyte	N	Slope	Intercept	R^2	Range
Na	55	1.0	5.2	0.99	35.4 - 193.8
K	55	1.0	0.03	1.00	1.80 - 8.61
Cl	55	1.0	4.6	1.00	21.4 - 192.1
Li	15	0.9	0.09	1.00	0.73 - 1.96

Mission Fluid Packs are substantially equivalent to Medica Fluid Packs. The Correlations exhibited slopes of 1 and R^2 of 1.00 to 0.99.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 2003

Diamond Diagnostics, Inc.
c/o Ms. Linda M. Stundtner
Mission Diagnostics
331 Fiske Street
Holliston, MA 01746

Re: k031159
Trade/Device Name: Mission Diagnostic Fluid Packs on MEDICA Electrolyte Analyzers
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: April 11, 2003
Received: May 27, 2003

Dear Ms. Stundtner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k(Number K031159

Device Name: Mission Diagnostic Fluid Packs on MEDICA Electrolyte Analyzers

Indication For Use:

- The products encompassed by this request are intended for in-vitro diagnostics use and are intended for use in calibrating the electrodes.
- Mission reagents are intended to serve as direct replacements to like named products manufactured by the OEM.
- The products encompassed are to be handled using normal laboratory precautions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrance of CDRH, Office of the Device Evaluation (ODE)

(Optional format 3-10-98)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031159

Prescription Use X